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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,790	07/20/2005	Margaret Forney Prescott	PD/4-32749A	2038

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ONE HEALTH PLAZA 104/3
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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,790	PRESCOTT, MARGARET FORNEY	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 8* is/are pending in the application.

4a) Of the above claim(s) *7 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/13/05, 4/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I and stents in the reply filed on April 20, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Group I consists of claims 1 – 6, not claims 1 – 7 as indicated in the previous action. Applicant indicted that claim 3 does not read on the elected invention, but as "a stent" is listed in line 4 of this claim, the Examiner has not withdrawn claim 3 from further consideration. The requirement is still deemed proper and is therefore made FINAL.

Comments and Notes

2. Two sets of claims were filed on the filing date of May 13, 2005. The original set of claims contains claims 1 – 9. The amended set of claims only contains claims 1 – 8 and the text ends in the middle page, indicating that no further text was provided by Applicant. In order to further prosecution of this application, a Notice of Non-Compliant Amendment has not been mailed but claim 9 and an appropriate status identifier for this claim must appear on all subsequent set of the claims filed.

Claim Objections

3. Claim 3 is objected to because of the following informalities: there is a typographical error present in line 3 in the word "administrati8on". Appropriate correction is required.

Claim Rejections - 35 USC § 112 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of inflammatory complications following vascular injury, does not reasonably provide enablement for the prevention of inflammatory complications following vascular injury. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The disclosure and claims of the application have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) as to undue experimentation

The factors include:

1. The nature of the invention;
2. The breadth of the claims;
3. The predictability or unpredictability of the art;
4. The amount of direction or guidance presented;
5. The presence or absence of working examples
6. The quantity of experimentation necessary;
7. The state of the prior art; and
8. The relative skill of those skilled in the art.

Each factor is address below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

1. The nature of the invention and the breadth of the claims:

Claim 6 is drawn to the use of pimecrolimus, as the free compound or a pharmaceutically acceptable salt thereof, in the preparation of a medicament for the prevention or treatment of inflammatory complications following vascular injury.

2. The amount of direction or guidance presented, the presence or absence of working examples: Pimecrolimus administration after vascular injury in rats using a implanted catheter to locally deliver the medicine reduced leukocyte infiltration into the vessel wall (example 1, p 14 – 15). In Example 2, vascular sections were procured and various stainings and examinations performed. Data analysis methods were presented

but the Examiner was unable to locate any specific data obtained from this experiment in the specification. The specification does indicate that lesion formation and the number of inflammatory cells was reduced in the areas surrounding the stent (top of p 16). A prophetic example regarding a protocol that could be used to demonstrate the effectiveness of local administration of pimecrolimus is presented (p 18). Stents containing pimecrolimus and the release rate of the drug from the prepared stents is presented (examples 3 – 5, p 16 – 17).

3. The quantity of experimentation necessary, the state of the prior art, and the relative skill of those skilled in the art: The relative skill of those skilled in the art is high, such as an M.D. or Ph.D. The prior art teaches that use of stent coatings and compositions can reduce the incidence of complications following vascular injury such as angioplasty and insertion of a stent (col 1, ln 12 – 23 of Hossainy et al. - US 6,153,252). To “prevent” is defined as “keep from happening or arising; make impossible" (definition of "prevent" from dicitonary.com, accessed 11/28/07). The state of art teaches that coated stents that locally deliver antiinflammatory or antiproliferative medications can reduce, but not eliminate, complications that occur after vascular injury. The experiments conducted by Applicant also indicate a reduction but not elimination of markers and complications caused by inflammation in the area surrounding stent implantation after vascular injury.

Since the term “treating” is inclusive of various administrative timing schemes and thus provides adequate coverage for all reasonably successful therapies

(prophylactic or active), the examiner recommends deleting the term "preventing" and simply reciting "treatment" only instead.

Claim Rejections - 35 USC § 112 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim provides for the use of pimecrolimus in the preparation of a medicament for the prevention or treatment of inflammatory complication following vascular injury, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. For the purposes of applying art below, this claim is being interpreted as a product claim.

8. Claims 3 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and

bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation “intraluminal or indwelling device adapted for local application or administrati8on in hollow tubes”, and the claim also recites stent, coated stent, and stent-graft, which are narrower statements of the limitation. Claim 6 recites the broad recitation “prevention and treatment of inflammatory complications following vascular injury”, and the claim also recites “treatment of intimal thickening or aneurysm expansion in vessel walls”, “stabilizing atherosclerotic plaques” and “stabilizing sites of aneurysm” which are narrower statements of the limitation.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

10. Claim 6 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252) in view of Baumann et al. (US 5,912,238).

Hossainy et al. discloses stents, intraluminal devices adapted for local application or administration in hollow tubes, coated with a polymer or polymer and pharmaceutical/therapeutic agent/drug (col 1, ln 25 - 27). The coatings can be used to deliver a variety of therapeutic and pharmaceutical agents, including compounds with antiproliferative, antiinflammatory or immunosuppressive activity (col 7, ln 56 – col 8, ln 35). Specific compounds identified include the macrolides tacrolimus (FK-506) and sirolimus (rapamycin; col 8, ln 30 – 32). These compounds are affixed to the medical device in a way allowing drug release.

Hossainy et al. does not disclose the inclusion of pimecrolimus in the drug delivery device.

Baumann et al. disclose macrolides compounds in the free or salt form are useful as antiinflammatory, immunosuppressant and antiproliferative agents (abstract, col 28, ln 64 – 67). Among the preferred compounds disclosed is the compound of Example 66a, 33-epi-33-chloro-FR-250 (col 30, ln 23), which is another name for pimecrolimus.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate pimecrolimus into the polymer coating of the stent disclosed by Hossainy et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Hossainy et al. discloses that compounds with antiinflammatory, immunosuppressant and antiproliferative activities, including the related macrolides tacrolimus and sirolimus, can be incorporated into stents and Baumann et al. teaches that pimecrolimus also possess these desirable pharmaceutical activities. Therefore,

pimecrolimus, tacrolimus and sirolimus (rapamycin) are functional equivalents as all the compounds are macrolides with antiinflammatory, immunosuppressant and antiproliferative activities.

"In preparation of a medicament for the prevention or treatment of inflammatory complications following vascular injury such as:…" in claim 6 has been treated as a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The structures taught by the cited art are capable of being used to treat inflammatory complications as the cited prior teaches the same type of medical device as claimed by Applicant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW